EXHIBIT E
INFORMATION TO ENABLE DETERMINATION
OF REGULATORY REVIEW PERIOD

Relevant Dates and Information to Enable
Determination of the Regulatory Review Period

The '195 patent claims a human drug product.

The Investigational New Drug (IND) application for the APTIVUS® product, IND No. 51979, was submitted on November 13, 1996, received by the FDA on November 14, 1996, and became effective 30 days after submission on December 13, 1996, pursuant to 21 C.F.R. §312.

The New Drug Application (NDA) for the APTIVUS® product, NDA No. 21-814, was submitted on December 21, 2004 and was approved by the FDA on June 22, 2005.